PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, June 24, 2003, 10:00 a.m., Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts. Public Health Council members present were: Ms. Christine Ferguson, Ms. Phyllis Cudmore, Mr. Manthala George, Jr., Mr. Albert Sherman, Ms. Janet Slemenda, and Dr. Martin Williams. Dr. Thomas Sterne, Ms. Maureen Pompeo, and Ms. Shane Kearney Masaschi absent. Also in attendance was Attorney Donna Levin, General Counsel.

Chair Ferguson announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with the Massachusetts General Laws, Chapter 30A, Section 11A ½.

The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Ms. Jean Flatley McGuire, Director, AIDS Bureau; Mr. Howard Wensley, Director, Division of Community Sanitation; Mr. Paul Tierney, Director, Food Protection Program; Ms. Nancy Ridley, Assistant Commissioner, Bureau of Health Quality Management; Ms. Louise Goyette, Director, Office of Emergency Medical Services; Ms. Joyce James, Director, Determination of Need Program; Dr. Paul Dreyer, Director, Division of Health Care Quality; and Deputy General Counsels: Edward Sullivan, Howard Saxner, and Carol Balulescu.

PERSONNEL ACTIONS:

In a letter dated June 10, 2003, Katherine Domoto, M.D., Associate Executive Director for Medicine, Tewksbury Hospital, Tewksbury, recommended approval of the appointments and reappointments to the medical staff of Tewksbury Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Associate Executive Director for Medicine of Tewksbury Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the following appointments and reappointments to the various medical staffs of Tewksbury Hospital be approved for a period of two years beginning June 1, 2003 to June 1, 2005:

APPOINTMENTS:	STATUS/SPECIALTY:	MEDICAL LICENSE NO.:
Seema Arora, MD	Provisional Affiliate Internal Medicine	154170
Kevin Grimes, PhD	Provisional Allied Psychology	3945

REAPPOINTMENTS:	STATUS/SPECIALTY:	MEDICAL LICENSE NO.:
Khatija Gaffar, MD	Active Internal Medicine	53316
Lisa Price, MD	Affiliate Psychiatry	205404
Syed Rahman, MD	Active Psychiatry	73277
Jeffrey Simmons, MD	Consultant Psychiatry	39537
Guillermo Walters, MD	Consultant Radiology	74668

In a letter dated June 9, 2003, Paul D. Romary, Executive Director, Lemuel Shattuck Hospital, Jamaica Plain, recommended approval of initial appointments and reappointments to the various medical staffs of Lemuel Shattuck Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted unanimously: That, in accordance with the recommendation of the Executive Director of Lemuel Shattuck Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointments and reappointments to the various medical staffs of Lemuel Shattuck Hospital be approved as follows:

APPOINTMENTS:	STATUS/SPECIALTY:	MEDICAL LICENSE NO.:
Hilary Aroke, MD	Internal Medicine Consultant	210218
Steven Benyas, MD	Psychiatry	211446
Jeffrey Cooper, MD	Surgery Consultant	79976
Elizabeth Egan, MD	Internal Medicine Consultant	217586
Terese Hammond, MD	Internal Medicine Consultant	216556
Marc Homer, MD	Radiology Consultant	35380
Ramina Jajoo, MD	Internal Medicine	205358

Nayer Nikpoor, MD	Radiology Consultant	73739
Roger Olade, MD	Internal Medicine	213595
Remi Rosenberg, MD	Internal Medicine Consultant	215394
Katja von Tiesenhausen, MD	Internal Medicine Consultant	216177

REAPPOINTMENTS:	**STATUS/SPECIALTY:**	**MEDICAL LICENSE NO.:**
Ioana Bica, MD	Active Internal Medicine	211797
Florine Haimovicic, MD	Psychiatry	206057
Violeta Kelly, MD	Active Anesthesia	35781
Timothy Pace, MD	Psychiatry	150244
Jeff Palacios, MD	Consultant Psychiatry	213034
Janice Rothschild, MD	Surgery Consultant	57559

In a letter dated June 5, 2003, Blake Molleur, Executive Director, Western Massachusetts Hospital, Westfield, recommended approval of an appointment to the consulting medical staff of Western Massachusetts Hospital. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted unanimously: That, in accordance with the recommendation of the Executive Director of Western Massachusetts Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the following appointment to the consulting medical staff of Western Massachusetts Hospital be approved:

APPOINTMENT:	**STATUS/SPECIALTY:**	**MEDICAL LICENSE NO.:**
Karl Coyner, MD	Radiology	211721

STAFF PRESENTATION: NO VOTE/INFORMATIONAL ONLY

"NATIONAL HIV COUNSELING AND TESTING WEEK: AN UPDATE ON PROGRESS IN MASSACHUSETTS", BY JEANNE FLATLEY MCGUIRE, DIRECTOR, AIDS/HIV BUREAU:

Ms. Jeanne Flatley McGuire, Director, AIDS/HIV Bureau, reported that HIV/AIDS cases are on the rise among 13 to 24 year olds. She said in part, "…Reported HIV/AIDS cases among 13 to 24 –year olds in Massachusetts have grown significantly in the four years since HIV surveillance began in 1999. In 2002, adolescents and young adults represented 8.7 percent of all HIV reports, up from 6.1 percent in 1999. Over this four-year period, 13 to 24-year olds have accounted for 301 of the 4,219 new cases reported to the state. Approximately 77 percent of new cases among adolescents and young adults are the result of intravenous drug use. Cities with the highest percentage of their recent HIV diagnoses occurring among 13 to 24-year-olds include Chelsea, Medford, Lawrence, Chicopee, Brookline, Somerville, Holyoke, Everett, Brockton and Revere…The relative number of new HIV/AIDS cases reported in people over 50 also increased significantly over the same period of time, with this group accounting for 12 percent of the reported cases in 2002, up from 9.2 percent in 1999. For 2001, the most recent year of report from the Pediatric Spectrum of Disease Study (PSD), the Department reports for the first time no infants known to have contracted HIV from their mothers. Since 1993, the Department's PSD project, a collaboration with the Centers for Disease Control, has tracked a decline in perinatal transmission from 22 percent of births to HIV positive women in that year to no known seroconversions in 2001. The Department is undertaking new targeted media campaigns to encourage HIV testing and plans to expand routine HIV counseling and testing in certain clinical sites in high prevalence areas. The Department is also finalizing criteria for the use of new HIV rapid testing products…..HIV testing related areas, identified nationally as part of the new CDC HIV prevention initiative, include improved prenatal testing, reduction of late diagnoses, and improved targeting of populations with rising incidence. The report included a review of these populations and of the rising risk among men who have sex with men. The Public Health Council also reviewed the performance of the four-year-old HIV surveillance system. The Council approved the implementation of this system in 1999. HIV cases are reported by code, not by name, in Massachusetts. Massachusetts has had 17,998 residents diagnosed with AIDS. Sixty percent of these residents have died. There are an estimated total of 19,000 to 21,000 residents living with HIV/AIDS and about one-quarter of these residents do not know their HIV status and/or have not been reported."

Chair Ferguson noted, "…These new statistics are alarming, even though the rate of HIV/AIDS among young people continues to be less here than in the rest of the country. We will work to improve our understanding of the risk to adolescents and young adults and focus prevention messages on these specific age groups….We cannot guarantee elimination of perinatal transmission of HIV, be we can continue to improve the

likelihood that every pregnant woman knows her status and has the best opportunity to prevent transmission to her child."

NO VOTE, INFORMATIONAL ONLY

REGULATIONS:

REQUEST FOR PROMULGATION OF AMENDMENTS TO 105 CMR 430.000: MINIMUM SANITATION AND SAFETY STANDARDS FOR RECREATIONAL CAMPS FOR CHILDREN, STATE SANITARY CODE, CHAPTER IV:

Mr. Howard Wensley, Director, Division of Community Sanitation, said, "The Department of Public Health is mandated by Massachusetts General Laws, Chapter 111, S127 A to promulgate regulations pertaining to Recreational Camps for Children. These regulations initially promulgated in the early 1960's have been amended several times. The initial regulations pertained solely to general environmental conditions such as space, food, water and sewage, but have become significantly more comprehensive to include issues of staff qualifications, ratios, program standards and background investigations of staff members. In addition to the recently promulgated emergency amendments to the regulations for Recreational Camps for Children, the Department also proposed several other routine amendments….These amendments propose: (1) changes to camper and staff immunization requirements; (2) additional language requiring any associated bathing beach be in compliance with the appropriate chapter of the State Sanitary Code; (3) that camp associated stables must be licensed in accordance with statute; and (4) the elimination of specific language regarding egress provisions by referencing the appropriate section of the Massachusetts State Building Code. During the informational presentation to the Public Health Council in February, a member of the Council asked for clarification regarding the change in the requirement that certain campers have a booster dose of tetanus within five years rather than the previously required 10 years. This change reflects the most recent recommendations of the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). A Td booster is essential to ensure long-lasting immunity against tetanus. According to the ACIP, lowering the age for administration of the first Td booster from ages 14-16 years to ages 11-12 years should increase compliance and thereby reduce the susceptibility of adolescents to tetanus and diphtheria. This recommendation reinforces a routine adolescent health visit for other preventative screening, care and counseling as well. The Public Health Council is respectfully requested to approve the regulations as amended."

After consideration, upon motion made and duly seconded, it was voted unanimously to **approve the Request for Promulgation of Amendments to 105 CMR 430.000: Minimum Sanitation and Safety Standards for Recreational Camps for Children, State Sanitary Code, Chapter IV**; that a copy of the approved regulations be forwarded to the Secretary of the Commonwealth; and that a copy of the amended regulations be attached to and made a part of this record as **Exhibit Number 14,760.** A notice of the public hearing and a request for comments were published in the Boston

Herald and Springfield Union. The hearing was held at the State Laboratory Institute on April 7, 2003 at the same time as the hearing for the emergency regulations. Twenty-three people attended the hearing with no one providing testimony on this set of proposed non-emergency regulations. A representative of the Department's Division of Communicable Disease Immunization Program provided additional language to clarify the appropriate age ranges for certain vaccines when the camper or staff person was either not in school or not attending a grade school.

REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO 105 CMR 561.000: FROZEN DESSERTS AND FROZEN DESSERT MIXES:

Mr. Paul Tierney, Director, Food Protection Program, presented the request for final promulgation of amendments to 105 CMR 561.000: Frozen Desserts and Frozen Dessert Mixes. He said, "The Department, through the Division of Food and Drugs (DFD), is authorized to adopt rules and regulations relative to sanitary conditions, testing requirements, and standards of identity for frozen desserts and frozen dessert mixes. DFD licenses out-of-state plants that sell their products in the Commonwealth, while local boards of health license in-state operations, both wholesale (ice cream plants) and retail ("scoop shops;" soft-serve machines). DFD advises local boards on questions that arise, and sometimes inspects in-state wholesale operations. The regulation governing these activities is entitled 105 CMR 561.000: Frozen Desserts and Frozen Dessert Mixes. Due to the significance and scope of the regulatory changes proposed, DFD is striking the current regulations and replacing them in their entirety. The proposed revision will bring the Massachusetts regulations into conformance with the U.S. Food and Drug Administration's (FDA's) regulations addressing the same issues. The new regulations incorporate by reference FDA regulations 21 CFR Part 110: Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food, and the standards of identity in 21 CMR Part 135: Frozen Desserts. The Department convened an advisory committee composed of representatives of in-state and out-of-state manufacturers of frozen desserts, local boards of health, and the FDA. Committee members provided DFD with oral and written comments both before and after the public hearing, many of which were incorporated into the amended regulation. The Department requests that the Public Health Council approve promulgation of the revisions to 105 CMR 561.000: Frozen Desserts and Frozen Dessert Mixes."

SIGNIFICANT PROVISIONS OF THE REVISION TO 105 CMR 561.000

- Adoption of Federal Regulation 21 CFR Part 110: Part 110 is the federal regulation that establishes good manufacturing practices for food products. Because Part 110 establishes a national baseline for sanitary procedures, DPH has adopted this regulation in recent years every time it has revised particular regulations regarding processing of various types of food. This allows Massachusetts-based firms to operate under consistent state and federal regulations.

- Adoption of Federal Regulation 21 CFR Part 135: Part 135 contains the federal standards of identity for frozen dessert products, which govern how these products

must be labeled. Massachusetts is preempted by federal law from adopting different standards of identity for products for which a federal standard exists.

- Handling of Products: The regulations add requirements for dealing with known allergens to ensure that the plant adheres to sanitary procedures throughout its operations. A product recall section has also been added setting forth procedures that manufacturers must follow when there is reason to recall a marketed product. By including cross-references to federal recall requirements, this section ensures that all recalls will be carried out under complementary procedures.

- Administration and Enforcement: These sections provide manufacturers with specific licensing requirements, which are similar to the administration and enforcement provisions of other food regulations enforced by DFD. These sections provide a number of options by which resolution of compliance issues can be achieved, and ensure that industry's due process rights are protected. They also contain procedures for inspection and reinstatement of a license after suspension, similar to the process described in the Department's milk regulations.

MAJOR CHANGES MADE TO THE REVISION OF 105 CMR 561.000 BASED UPON PUBLIC HEARING TESTIMONY:

- To eliminate confusion, the U.S. Public Health Service "Grade A" Pasteurized Milk Ordinance (PMO) was not adopted in the regulations. Frozen desserts are not considered a "Grade A" product. Instead, specific pasteurization requirements that apply to milk-based frozen desserts were added to the regulations.

- Based upon current industry practices, the required core temperature of frozen products in transportation was raised from 0 degrees F to 10 degrees F. This change does not affect the safety of the products for consumers.

- To minimize burdens on the industry, the frequency of required cleaning and sanitizing of holding tanks containing unpasteurized ingredients was extended to from 72 to 96 hours. Plants that wish to hold product longer than this may apply to DPH for a variance and explain how product safety will be maintained. In addition, a temperature-recording device will only be required for new tanks put into service after the effective date of the new regulations.

- Requirements for bacterial testing of new and seasonal products were revised to account for the fact that some of these products are produced in very small quantities. These products will be placed into the appropriate testing categories that apply to other frozen dessert products.

- The standard of identity for "frozen dietary dairy desserts" was eliminated, as it conflicted with federal law.

After consideration, upon motion made and duly seconded, it was voted unanimously: **to approve the Request for Final Promulgation of Amendments to 105 CMR 561.000: Frozen Desserts and Frozen Dessert Mixes**; that a copy of the approved regulations be forwarded to the Secretary of the Commonwealth for promulgation; and that a copy of the amended regulations be attached to and made a part of this record as **Exhibit Number 14,761**. A public hearing was advertised and held on November 19, 2002. Eleven parties attended the hearing and submitted comments.

REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO 105 CMR 170.000: EMERGENCY MEDICAL SERVICES SYSTEM: 105 CMR 171.000: MASSACHUSETTS FIRST RESPONDER TRAINING; AND 105 CMR 172.000: RELATING TO THE REPORTING OF INFECTIOUS DISEASES DANGEROUS TO THE PUBLIC HEALTH:

Ms. Nancy Ridley, Assistant Commissioner, Bureau of Health Quality Management, said in part, "…The purpose of this memorandum is to request the Public Health Council's approval to promulgate final amendments to 105 CMR 170.000: Emergency Medical Service System: 105 CMR 171.000: Massachusetts First Responder Training; and 105 CMR 172.000: Relating to the Reporting of Infectious Diseases Dangerous to the Public Health. These amendments were originally presented to the Public Health Council on an informational basis on December 18, 2001, and again on December 17, 2002. The regulations for which approval to promulgate is being requested primarily implement two additional elements of "EMS 2000," service zone planning for organizing local emergency medical services (EMS) resources and delivery, and EMS first response. The amendments include other changes for improving program administration, such as additional medical oversight and new reporting requirements for ambulance services, and adding new definitions and provisions to reflect current standards in EMS practice and EMT and first responder training…"

Ms. Louise Goyette, Director, Office of Emergency Medical Services, said in part, "…Under EMS 2000, service zone planning is at the heart of community-based EMS service delivery. The statute calls for local jurisdictions to develop service zone plans to coordinate, integrate and implement EMS delivery. Communities, to a large extent, currently engage in this process when they make mutual-aid agreements or enter into contracts for the provision of ambulance service. Service zone planning will require a more formalized accounting of all EMS resources, setting local EMS performance standards, choosing service zone providers, and developing an operational plan for response to emergency ambulance calls. Communities may do individual service zone planning or collaborate with other communities. The Regional EMS Councils will serve as resources to communities, provide technical assistance and conduct the initial review

of the service zone plans. The Regional EMS Councils and the Department have already begun educating local community officials regarding service zones and will continue doing so during the implementation period. The Department has the ultimate authority to approve service zone plans and the designation of service zone providers within those plans. Related to service zone planning is the new voluntary category of EMS service created by EMS 2000, called "EMS first response." EMS first response is the rapid response and initiation of EMS at the scene of a medical emergency, prior to the arrival of an ambulance service, by a service that is 1)licensed, and its responding crew certified, by the Department. 2) a private or public entity, 3) designated in a service zone plan and 4) integrated into the EMS system. This distinguishes EMS first response from first responder agencies and first responders that are largely police and fire agencies and personnel, mandated under state law to be trained to provide a basic level of first aid and cardiopulmonary resuscitation (CPR). First responder agencies have no mandate to be dispatched to EMS calls. They are not licensed and their personnel are not required to be certified by the Department. The requirements on first responder agencies and first responders are not affected by the EMS first response regulations. To further define EMS first response services, the Department convened an EMS first response planning group, made up of interested parties representing the public, private and volunteer ambulance and first responder agency sectors, Regional EMS Councils and the Massachusetts Municipal Association, whose advice helped shape the provisions set out in these regulations. Under EMS 2000 and these proposed regulations, local jurisdiction(s) may choose to designate one or more EMS first response services, but are not obligated to do so. If designated, an EMS first response service would have a defined role in the service zone plan and a duty to respond to EMS calls in accordance with that plan. The Department would license these services and would certify their EMS first responders, if they are not already certified as EMTs."

Ms. Goyette continued, "After initially setting public hearings for these regulations in February 2002, the Department was informed by certain interested parties that there was still confusion about service zone planning, in particular with regard to the role of private ambulance services providing primary ambulance response to health care facilities pursuant to provider contracts. The Department postponed the public hearings and convened talks with representatives of associations that had raised the need for further clarification. During the next several months, the Department met with these organizations, as well as with other EMS stakeholder groups who requested meetings with regard to service zone planning, and ultimately added further clarification with regard to primary ambulance response under provider contract. Those additions were then submitted to the Department's Emergency Medical Care Advisory Board in August 2002 for its review and comment prior to rescheduling public hearings. The Department held three public hearings in October 2002: One in Northampton, one in Waltham and one in Brockton. The Department reviewed the comments, incorporated some of the suggestions, and returned to Public Health Council seeking final promulgation on December 17, 2002. At that time, the Public Health Council voted to postpone a decision on the regulations for at least 90 days, and asked the Department to hold a fourth public hearing to gather more information, especially on two particular issues raised by the previous public comments. These issues were: 1) Whether the Department should

establish a requirement for regionalized advanced life support (ALS) ambulance services or a Determination of Need-like process for ALS as a mandatory condition of service zone planning, and 2) In addition to recognizing private ambulance service provider contracts with health care facilities (e.g., nursing homes), whether the regulations should recognize private provider contracts for emergency ambulance response with health insurance plans or assisted living facilities where there are no health care professionals on site, without separate service zone approval. This additional hearing was held February 11, 2003 in Waltham. Four members of the Public Health Council attended the public hearing. Oral and written testimony was extensive. In order to accommodate the Public Health Council's request for additional information from the public, the Department provided a stenographer to record oral testimony, and established a page on the Department website for written testimony to be made accessible to the Public Health Council members and the public. On March 27, the Department provided the Public Health Council with the printed transcript of the oral testimony, hard copies, copies of written testimony that came in paper form only, and the website address for viewing electronically transmitted written comment.

Because the comments generated by this last public hearing and comment period were varied and often comprehensive, and because the Public Health Council has had access to all the testimony, the Department will not summarize the comments in detail here. The vast majority of the testimony addressed the two issues on which the Public Health Council sought further comment. By a two-to-one margin, most of the commentators who addressed the ALS regionalization question did not favor such an approach, and asked that ALS service designation be left to the local community as part of service zone planning. On the second issue, with regard to further extending protections for private provider contracts with facilities with no health care professionals on site, all the commentators, with the Mass. Extended Care Federation, opposed providing such protections, and, in fact, most advocated for further restricting the recognition of such private provider contracts. Other comment addressed a number of other issues. Since the hearing, the Department has carefully considered all the testimony. Those advocating for a mandatory regionalized or DON-like requirement for ALS repeatedly raised concerns about the quality of medical oversight. As a result, the Department proposes to incorporate additional requirements for medical oversight with respect to ambulance or EFR service at the ALS level. In addition, in response to comment by the Massachusetts Municipal Association with regard to communities' current fiscal difficulties, the Department has extended by 19 months the outside deadline for local jurisdictions to be under a Department-approved service zone plan, to December 31, 2006. The Department asks that these regulations be approved for final promulgation as presented today."

Ms. Goyette concluded, "In 105 CMR 170.355, the Department deleted the requirement pertaining to ambulance services with provider contracts notifying EFR services when they are providing primary ambulance response, if the service zone plan so required. This deletion, in response to comment from the Massachusetts Ambulance Association and the Massachusetts Extended Care Federation, was made in order to simplify the regulatory structure and leave such matters of coordination of response to the local communities in service zones. In further response to concerns raised by the

Massachusetts Ambulance Association regarding the service zone planning process, the Department clarified the new definition for "immediate dispatch," in response to comment from the Massachusetts Call/Volunteer Firefighters Association …"

Changes Made in Response to Comments

1. **Medical Oversight** The current basis for medical oversight of ALS services in the Commonwealth is through the affiliation agreements with hospitals that ALS services are required to maintain under 105 CMR 170.300. The Department made the following changes in order to strengthen the existing requirements of medical oversight.

"Authorization to Practice" definition (170.020) – The Department amended this definition to clarify that it is the medical director named under the affiliation agreement of the ALS service who authorizes certified ALS providers to work and receive medical control pursuant to their services' affiliation agreement and in conformance with the Statewide Treatment Protocals.

Affiliation agreements (170.300)– The Department amended and expanded the requirements for what must be addressed in an affiliation agreement between ALS ambulance and EFR services and hospitals for medical oversight, to include the following: 1) explicit designation of an affiliate hospital medical director, who has authority over the clinical and patient care aspects of the affiliated EMS service, including authorization to practice of ALS personnel; 2) clarification that on-line medical direction must be provided by physicians 24 hours a day, 7 days a week, in accordance with the Statewide Treatment Protocols; 3) operation of a quality assurance/quality improvement (QA/QI) program coordinated by the affiliate hospital medical director and with participation of the service medical director, if different from the affiliate hospital medical director, and on-line medical direction physicians: 4) operation of a program for skill maintenance and review for EMS personnel; 5) assurance that EMS personnel have access to remediation, training and retraining as necessary, under the oversight of the affiliate hospital medical director or his/her designee; 6) clarification that regular consultation between hospital medical and nursing staff and the ALS personnel include but not be limited to attendance at morbidity and mortality rounds and chart reviews, and 7) clarification that the on-line medical direction between physician and ALS personnel regarding a particular patient's condition and care must be recorded, and that when physicians order medication or a particular treatment for a patient, the physician or his/her designee must sign the trip record documenting the patients's care by the ALS personnel.

Memorandum of Agreement for ALS-Level EFR Services (170.307) – The Department added the requirement that the protocols for medical control and medical direction under these memoranda of agreement between ALS-level EFR services and ALS-level ambulance services at a minimum confirm that the ALS-level EFR service's current affiliation agreement complies with all the regulatory requirements for affiliation agreements, as now augmented.

Elements of a Service Zone Plan: Medical Oversight (170.510(G)) - The Department added to required element (G), regarding the inclusion of a plan for medical control, the requirement that at a minimum, such a plan consist of collection, review and monitoring of current affiliation agreements that are consistent will all the regulatory requirements for affiliation agreements, as now augmented, for all services operating in the service zone.

II. **Deadline for Service Zone Planning**

Distribution and Use of Department Funds by Regional EMS Councils (170.106); Responsibility to Dispatch, Treat and Transport (170.355); Review and Approval of Service Zone Plans (170.530) – The Department extended by 18 months the outside deadline by which each local jurisdiction would have to covered by a service zone plan, in accordance with which primary ambulance response is carried out, from July 1, 2005 to December 31, 2006.

III Service zone plan development participation; EFR notification of primary ambulance service calls performed pursuant to provider contracts

EFR notification for primary ambulance response by ambulance services with provider contracts (170.355(B)(3)(b)) – The Department deleted that provision that ambulance services responding to such are to notify EFRs if required by the service zone plan. This simplifies the regulation while leaving such matters of coordination of response to the local communities in the service zone.

Service Zone Plans (170.500(B)) – The Department added to the required element (B), regarding the local jurisdictions' responsibility to develop service zone plan, the requirement that communities do so with direct input from the following parties operating in their service zone: First responder agencies, EFR services, all ambulance services providing primary ambulance response pursuant to provider contracts, and all other ambulance services.

Clarification of Immediate Dispatch Definition

"Immediate dispatch" definition (170.020) – The Department added a sentence to clarify that toning out or calling for on-call or volunteer personnel to respond to and staff an ambulance is included within the definition of immediate dispatch.

After consideration, upon motion made and duly seconded, it was voted unanimously to **approve the Request for Final Promulgation of Amendments to 105 CMR 170:000: Emergency Medical Services System: 105 CMR 171.000: Massachusetts First Responder Training; and 105 CMR 172.000: Relating to the Reporting of Infectious Diseases Dangerous to the Public Health**; that a copy of the regulations be attached to and made a part of this record as **Exhibit Number 14,762.**

REQUEST FOR EMERGENCY PROMULGATION OF PROPOSED AMENDMENT TO DETERMINATION OF NEED REGULATIONS 105 CMR 100.000 GOVERNING APPLICATION FILING DAYS FOR INNOVATIVE SERVICES AND NEW TECHNOLOGY:

Ms. Joyce James, Director, said in part, "The purpose of this memorandum is to request the Public Health Council's action on the emergency promulgation of the proposed amendment to the Determination of Need Regulations 105 CMR 100.302, Filing Days for Applications and Amendments. Under the Determination of Need (DoN) Regulations, the filing days of applications for innovative service or new technology are on the first business days of February and August of each year. The proposed amendment will delay the filing of applications for Neonatal Intensive Care Units (NICU), defined by the Department as an innovative service, until the first business day of August 2004. This amendment will be effective upon filing with the Secretary of State's office and will remain in effect for ninety days. On July 23, 2002, the Council adopted revisions to the health care requirements section of the January 28, 1997 Determination of Need Guidelines for Neonatal Intensive Care Units (NICU). The revisions projected a statewide need for twenty-five beds in 2005. On November 19, 2002, the Council approved the application filed by South Shore Hospital for ten of these 25 NICU beds. On January 28, 2003, the Council approved emergency promulgation of an amendment to 105 CMR 100.302 to delay the filing days of applications for NICUs until the first business day of August 2003. In the intervening time, the Department has reopened discussions with existing providers of neonatal intensive care services and members of the Department's Perinatal Advisory Committee. The purpose of these discussions is to explore alternatives to the determination of need process to maintain high quality care in the delivery of neonatal intensive care services while addressing the shortage of NICU beds statewide. The proposed amendment to delay the next filing day for NICU applications until the first business day of August, 2004 is necessary to allow these discussions to continue until the Department has decided on the most effective and cost efficient manner to regulate neonatal intensive care services. Department staff will hold a public hearing on the proposed amendment and return to Council, within the 90-day period, with the proposed final regulation for Council's adoption.

After consideration, upon motion and made and duly seconded, it was voted [Chair Ferguson, Ms. Cudmore, Mr. George, Jr., Ms. Slemenda, Mr. Williams in favor; Mr. Sherman out of the room during vote] unanimously to **approve the Request for Emergency Promulgation of Proposed Amendment to Determination of Need Regulations 105 CMR 100.000 Governing Applications Filing Days for Innovative Services and New Technology** and that a copy of the approved amendment be forwarded to the Secretary of the Commonwealth; and that a copy of the regulation be attached to and made a part of this record as **Exhibit Number 14,763.**

DETERMINATION OF NEED PROGRAM:

ALTERNATE PROCESS FOR TRANSFER OF OWNERSHIP APPLICATIONS:

PROJECT APPLICATION NO. 5-3A56 OF 4499 ACUSHNET AVENUE OPERATING COMPANY, LLC D/B/A NEW BEDFORD REHABILITATION HOSPITAL REQUEST FOR TRANSFER OF OWNERSHIP AND ORIGINAL LICENSURE OF MEDIPLEX REHABILITATION HOSPITAL, RESULTING FROM THE TERMINATION OF THE LEASE AND TRANSFER OF OPERATIONS FROM MEDIPLEX REHABILITATION OF MASSACHUSETTS, INC. AND ITS AFFILIATES TO 4499 ACUSHNET AVENUE OPERATING COMPANY, LLC PURSUANT TO A CHAPTER 11 BANKRUPTCY STIPULATION AND ORDER:

Ms. Joyce James, Director, Determination of Need Program, said in part, "…4499 Acushnet Avenue Operating Company, LLC, d/b/a New Bedford Rehabilitation Hospital, with a place of business at 411 Hackensack Avenue, Hackensack, New Jersey, is seeking Determination of Need for transfer of ownership and original licensure of Mediplex Rehabilitation Hospital located at 4499 Acushnet Avenue, New Bedford, MA. The transfer of ownership results from the termination of the lease and transfer of operations of Mediplex Rehabilitation of Massachusetts, Inc., and its affiliates d/b/a Mediplex Rehabilitation Hospital to 4499 Acushnet Avenue Operating Company, LLC, pursuant to a Chapter 11 Bankruptcy Stipulation and Order of the Bankruptcy Court in Wilmington, DE. 4499 Acushnet Avenue Operating Company, LLC will become the licensee of the Hospital. No change in services and no capital expenditure are contemplated for this transfer of ownership. Based upon a review of the application as submitted and clarification of issues by the Applicant, Staff finds that the application satisfies the requirements for the Change of Ownership found in 105 CMR 100.600 et seq. Staff also finds that the Applicant satisfies the standards applied under 100.602 as follow:

A. Individuals residing in the Hospital's health systems area will comprise a majority of the individuals responsible for decision concerning:

1. approval of borrowings in excess of $500,000;
2. additions or conversions which constitute substantial change in services;
3. approval of capital and operating budgets; and
4. approval of the filing of an application for determination of need.

B. The Division of Medical Assistance did not submit any comments on access problems for Medicaid recipients in the Hospital's primary service area.

C. The Division of Health Care Quality has determined that the Applicant and any health care facility affiliates have not been found to have engaged in a pattern or practice in violation of the provisions of M.G.L. c.111, s.51(D).

D. The Department has determined that the Applicant, a non-acute care hospital, is not subject to a condition of approval to maintain or increase the percentage of gross patient service revenues, as defined at M.G.L. c.6A, s.31, allocated to bad debt and free care for a period of twenty-four months after the proposed transfer has taken place.

E. The Division of Health Care Quality has confirmed that the Applicant is an affiliate of a hospital licensed by the Department.

After consideration, upon motion made and duly seconded, it was voted unanimously, [Chair Ferguson, Ms. Cudmore, Mr. George, Jr., Ms. Slemenda, Mr. Williams in favor; Mr. Sherman was not in room during vote] that **Project Application No. 5-3A56 of 4499 Acushnet Avenue Operating Company, LLC d/b/a New Bedford Rehabilitation Hospital, be approved**, based on staff findings; and that a copy be attached to and made a part of this record as **Exhibit No. 14, 764.**

The meeting adjourned at 11:15 a.m.

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Christine Ferguson, Chair
Public Health Council

LMH/sb